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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|----------------|----------------------|-------------------------|-----------------|
| 10/032,801 | 12/27/2001 | Anthony D. Gonzalez | 682.0023USU | 7223 |
| 7 | 590 02/25/2004 | | EXAM | INER |
| Charles N.J. Ruggiero, Esq. | | | BENNETT, RACHEL M | |
| Ohlandt, Greeley, Ruggiero & Perle, L.L.P. | | | ART UNIT | PAPER NUMBER |
| One Landmark Square | | | 1615 | |
| Stamford, CT 06901-2682 | | | DATE MAILED: 02/25/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. | Applicant(s) |
| Office Action Summary | 10/032,801 | GONZALEZ ET AL. |
| Office Action Summary | Examiner | Art Unit |
| TI MAN NO DATE CHI | Rachel M. Bennett | 1615 |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the | correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ti y within the statutory minimum of thirty (30) da vill apply and will expire SIX (6) MONTHS fron , cause the application to become ABANDON | rimely filed sys will be considered timely. In the mailing date of this communication. ED (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on 26 No. 2a) This action is FINAL. 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pr | · · |
| Disposition of Claims | | |
| 4) Claim(s) 1-50 is/are pending in the application. 4a) Of the above claim(s) 22,25-36 and 48 is/ar 5) Claim(s) is/are allowed. 6) Claim(s) 1-21,23,24,37-47,49 and 50 is/are rejuice. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or | re withdrawn from consideration ected. | |
| Application Papers | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the order of the | epted or b) objected to by the drawing(s) be held in abeyance. Se ion is required if the drawing(s) is of | ee 37 CFR 1.85(a). Djected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | • | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicat rity documents have been receiv u (PCT Rule 17.2(a)). | tion No red in this National Stage |
| | | |
| Attachment(c) | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other: | |

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DETAILED ACTION

Election/Restrictions

1. This application contains claims 22, 25-36 and 48 drawn to an invention nonelected with traverse on April 14, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 4. Claims 1-21, 23-24, 37-47, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (EP 1136064 A2), and further in view of Garrison et al. (US 6355264 B1).

Applicants claim a hybrid silicone powder matrix comprising a hybrid silicone powder and a volatile silicon.

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Anderson discloses a topical composition having a spherical and/or substantially spherical optical diffuser particle and crosslinked silicone elastomer. See abstract. More specifically, the compositions include the use of a crosslinked silicone elastomer in combination with a substantially spherical, preferably perfectly spherical, particle having a narrow particle size distribution. Examples of suitable spherical particles include silicone powder. The spherical particles are present in an amount from about 0.01% to about 10%. The crosslinked silicone elastomers are form a divinyl compound having a siloxane polymer preferably having at least two free vinyl groups. The divinyl compound reacts with Si-H linkages of a polysiloxane backbone. The crosslinked silicone elastomer can be non-emulsifying (e.e., polyoxyalkylene groups absent) or emulsifying (i.e. polyoxyalkylene groups present). Examples of suitable crosslinked silicone elastomers include, dimethicone crosspolymer, organopolysiloxane, polysilicone-11 and dimethicone/vinyl dimethicone crosspolymer and mixtures thereof. See cols. 3 and 4. The composition may also include pharmaceutical actives and excipients. Suitable actives include salicylic acids, insect repellents, and sunscreen. See cols. 5 and 6. Anderson does not disclose the silicone powder matrix to include a volatile silicone.

Garrison et al. discloses an insect repellent composition suitable for topical application. The insect repellent may also contain a sunscreen. See abstract. The insect repellent may be oil of citronella. The vehicle may also contain up to 50% of a volatile silicone. The volatile silicone acts to improve the feel of the insect repellent composition against the skin. The preferred volatile silicone is cyclomethicone. See page 4.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the

composition of Anderson by adding a volatile silicone, specifically cyclomethicone, as taught by Garrision because of the expectation of improving the feel of the insect repellent composition against the skin as taught by Garrison. The expected result would be a topical composition comprising a hybrid silicone powder matrix, an active ingredient and a volatile silicone.

Response to Arguments

- 5. Applicant's arguments filed 11/26/03 have been fully considered but they are not persuasive.
- 6. Applicants argue the prior art does not teach or suggest to one of ordinary skill in the art that the volatile silicone, would cause swelling of the hybrid polymer. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., swelling of the hybrid polymer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Also, Applicants submit that there is also not basis to conclude that a time or controlled release benefit would be obtained. The examiner refers to Anderson, where the composition may include pharmaceutical actives and excipients. Therefore, it is the position of the examiner the limitation "time/controlled release composition" is met because Anderson discloses excipients in the composition, which are known in the art to determine the time release of the active ingredient. No specific release profile of the active ingredient is claimed. Thus, the rejection is maintained.

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Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (571) 272-0589. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmb

James M. Spear JAMES M. SPEAR PRIMARY EXAMINER